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AstraZeneca

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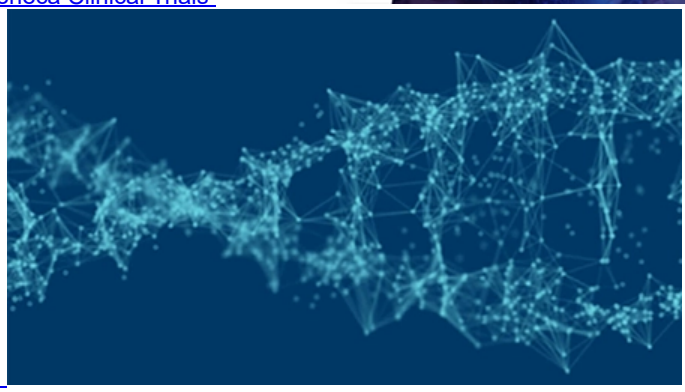
Featured website AstraZeneca Clinical Trials Featured website Open Innovation 

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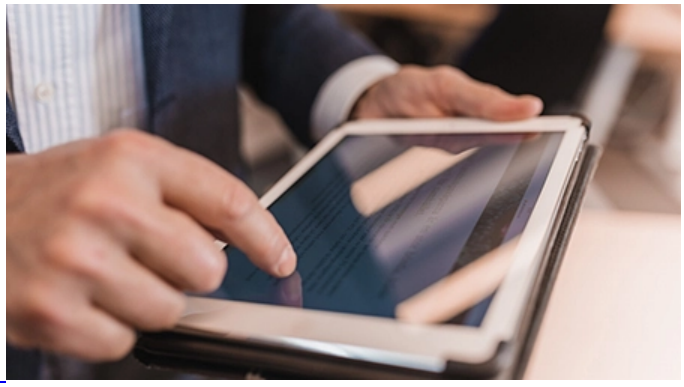

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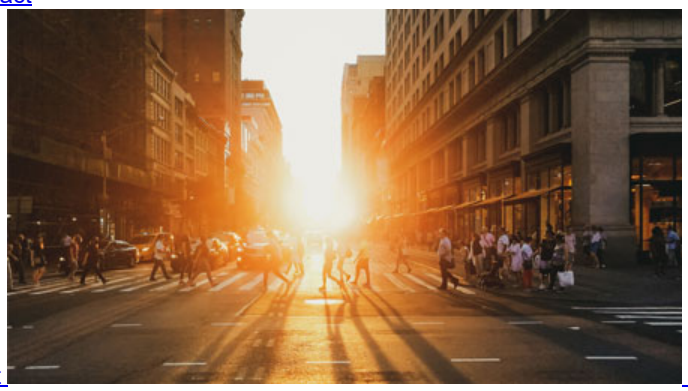

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Evusheld long-acting antibody combination approved for prevention and treatment of COVID-19 in Japan

PUBLISHED 30 August 2022

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First global approval for Evusheld as a COVID-19 treatment

PROVENT Phase III prevention trial showed reduced risk of developing symptomatic COVID-19

TACKLE Phase III treatment trial showed reduced risk of severe COVID-19 or death in high-risk patients

AstraZeneca's *Evusheld* (tixagevimab and cilgavimab, formerly AZD7442), a long-acting antibody combination, has been approved in Japan for both prevention (pre-exposure prophylaxis) and treatment of symptomatic disease caused by SARS-CoV-2 infection. The decision marks the first global marketing approval for *Evusheld* as a treatment for COVID-19.

In prevention, Japan's Ministry of Health, Labour and Welfare (MHLW) granted *Evusheld* Special Approval for Emergency for adults and adolescents (12 years of age and older weighing at least 40kg). *Evusheld* is approved for use in those whom SARS-CoV-2 vaccination is not recommended and who may have an inadequate response to a COVID-19 vaccine due to immunodeficiencies. Recipients of *Evusheld* for prevention should not be currently infected with or have had recent known exposure to a person infected with SARS-CoV-2.

In treatment, *Evusheld* is approved for adults and adolescents (12 years of age and older weighing at least 40kg) with risk factors for severe SARS-CoV-2 infection who do not require supplemental oxygen.

Kazuhiro Tateda, M.D. Ph.D., Professor, Department of Microbiology and Infectious Disease, Toho University, Tokyo, Japan, said: "COVID-19 continues to have a significant impact on our daily lives in Japan. Many people, including older adults, patients with comorbidities, and immunocompromised patients, remain at risk for poor outcomes from severe COVID-19. *Evusheld* will be a much-needed new option, offering long-term protection for those who do not achieve an adequate immune response after vaccination and helping prevent severe disease and death in those who do become infected."

Itaru Matsumura, M.D., Ph.D. Professor & Chairman, Department of Hematology & Rheumatology, Kindai University Faculty of Medicine, Otsuka, Japan, said: "Despite the progress of vaccinations and stringent safety precautions, there are very large number of new infections in Japan. The approval of *Evusheld* is expected to provide a non-vaccine prophylactic option for those who cannot expect a full immune response from COVID-19 vaccination, such as patients with blood cancers."

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, AstraZeneca, said: "The approvals of *Evusheld* in Japan represent an important milestone in our ongoing efforts to help combat COVID-19 on all fronts. *Evusheld* is now the only long-acting antibody combination authorised for both COVID-19 prevention and treatment, allowing us to help protect even more vulnerable patients such as the immunocompromised from this devastating disease."

The Japanese government has agreed to purchase 300,000 units of *Evusheld* (150mg each of tixagevimab and cilgavimab), and AstraZeneca is working with the government and partners to make first doses available as soon as possible.

The approvals were based on efficacy and safety data from the *Evusheld* clinical development programme, including the PROVENT Phase III pre-exposure prophylaxis trial, the TACKLE Phase III outpatient treatment trial, and Phase I trials, including in Japan. In PROVENT, a 300mg intramuscular (IM) dose of *Evusheld* significantly reduced the risk of developing symptomatic COVID-19 by 77% (95% confidence interval (CI): 46, 90; p<0.001) COVID-19 compared to placebo at the primary analysis.[1] An 83% (95% CI: 66, 91) relative risk reduction was shown at a six-month median follow-up analysis, with protection from the virus lasting six months.[1]

In TACKLE, a 600mg IM dose of *Evusheld* significantly reduced the relative risk of progressing to severe COVID-19 or death (from any cause) by 50% (95% confidence interval [CI] 15, 71; p=0.010) through day 29 compared to placebo in non-hospitalised patients with mild-to-moderate COVID-19 who were symptomatic for seven days or less, the trial's primary endpoint.[2] In pre-specified analyses of participants who received treatment within three days of symptom onset, *Evusheld* reduced the risk of developing severe COVID-19 or death (from any cause) by 88% compared to placebo (95% CI 9, 98), and the risk reduction was 67% (95% CI 31, 84) when participants received *Evusheld* within five days of symptom onset.[2]

Evusheld was generally well-tolerated in the trials.[1,2]

The recommended dose for prevention of symptomatic disease caused by SARS-CoV-2 infection in Japan is 150mg of tixagevimab and 150mg of cilgavimab, administered as separate sequential IM injections. Depending on the prevalence of SARS-CoV-2 variants, 300mg of tixagevimab and 300mg of cilgavimab may be administered for prevention. The recommended dose for treatment of COVID-19 is 300mg of tixagevimab and 300mg of cilgavimab, administered as separate sequential IM injections.

Evusheld has been shown to retain *in vitro* neutralisation activity against the main Omicron variants currently circulating globally, including BA.5 and BA.2.[3,4]

Evusheld is also authorised for use for pre-exposure prophylaxis (prevention) of COVID-19 in the US (emergency use), EU and many other countries. Regulatory submissions are progressing for both prevention and treatment indications around the world.

Notes

Evusheld
Evusheld, formerly known as AZD7442, is a combination of two long-acting antibodies - tixagevimab (AZD8895) and cilgavimab (AZD1061) - derived from B-cells donated by convalescent patients after SARS-CoV-2 infection. Discovered by Vanderbilt University Medical Center and licensed to AstraZeneca in June 2020, the human monoclonal antibodies bind to distinct sites on the SARS-CoV-2 spike protein[5] and were optimised by AstraZeneca with half-life extension and reduction of Fc effector function and complement C1q binding.[6] The half-life extension more than triples the durability of its action compared to conventional antibodies; [7-9] data from the PROVENT Phase III trial show protection lasting six months.[1] The reduced Fc effector function aims to minimise the risk of antibody-dependent enhancement of disease - a phenomenon in which virus-specific antibodies promote, rather than inhibit, infection and/or disease.[10]

The primary data supporting the *Evusheld* pre-exposure prophylaxis authorisations are from the ongoing PROVENT Phase III pre-exposure prevention trial, published in The New England Journal of Medicine, which showed a statistically significant reduction (77% at primary analysis, 83% at median six-month analysis) in the risk of developing symptomatic COVID-19 compared to placebo, with protection from the virus lasting six months.[1] More than 75% of PROVENT participants at baseline had co-morbidities that put them at high risk for severe COVID-19 if they were to become infected, including people who are immunocompromised and may have an inadequate immune response to COVID-19 vaccination.

Detailed results from the TACKLE Phase III outpatient treatment trial, published in *The Lancet Respiratory Medicine*, showed *Evusheld* provided clinically and statistically significant protection against progression to severe COVID-19 or death from any cause compared to placebo, with treatment with *Evusheld* earlier in the disease course leading to more favourable outcomes.[2] TACKLE was conducted in non-hospitalised adults with mild-to-moderate COVID-19 who were symptomatic for seven days or less. 90% of participants were at high risk of progression to severe COVID-19 due to age or co-morbidities, including cancer, diabetes, obesity, chronic lung disease or asthma, cardiovascular disease or immunosuppression.

Evusheld is being developed with support from the US government, including federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority in partnership with the Department of Defense; Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, under Contract No. W911QY-21-9-0001.

Under the terms of the licensing agreement with Vanderbilt, AstraZeneca will pay single-digit royalties on future net sales.

AstraZeneca
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Contacts
For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

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